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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Martin D. Moynihan
PRTSI, Inc.
P.O. Box 16446
Arlington, VA 22215

EXAMINER	
DAY, HERNG DER	
ART UNIT	**PAPER NUMBER**
2128	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/19/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/647,796	GLOZMAN ET AL.	
	Examiner	Art Unit	
	Herng-der Day	2128	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 January 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16,18-39 and 41-45* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16,18-39 and 41-45* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *04 January 2007* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This communication is in response to Applicants' Response ("Response") to Office Action dated September 8, 2006, filed January 4, 2007.

1-1. Claims 1-2, 4-6, 8-15, 18-20, 23-37, 39, and 43 have been amended. Claims 17 and 40 have been canceled. Claims 1-16, 18-39, and 41-45 are pending.

1-2. Claims 1-16, 18-39, and 41-45 have been examined and rejected.

Drawings

2. The replacement sheets of drawings are objected to for the following reason. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include **all** of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the Examiner, the Applicants will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

2-1. As shown in Fig. 11, it appears that the "osteotmy" as described in the block of "Application of a template for specific osteotmy such as Hallux Valgus" should be "osteotomy".

Claim Objections

3. Claim 1 is an independent method claim comprising a plurality of steps in the claim. Claim 23 is an independent apparatus claim comprising a plurality of means for functions in the claim. Where a claim sets forth a plurality of elements or steps, each element or step of the claim should be separated by a line indentation, 37 CFR 1.75(i). There may be plural indentations to further segregate subcombinations or related steps. See MPEP § 608.01(m).

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 18-19 and 41-42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5-1. Claim 18 depends on the canceled claim 17.

5-2. Claim 19 depends on the canceled claim 17.

5-3. Claim 41 depends on the canceled claim 40.

5-4. Claim 42 depends on the canceled claim 40.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 1-16, 18-39, and 41-45 are rejected under 35 U.S.C. 102(e) as being anticipated by Krause et al., U.S. Patent 6,711,432 B1 issued March 23, 2004 and filed October 23, 2000.

7-1. Regarding claim 1, Krause et al. disclose a method for preoperative planning and simulating of an orthopedic surgical procedure to be performed on an anatomical structure, using medical images of the anatomical structure, comprising inter alia:

a. obtaining and displaying the medical images of the anatomical structure (X-ray or fluoroscopic images of a patient's bone, column 6, lines 18-20; several regular X-ray images of the patient, column 6, lines 42-51);

b. segmenting the anatomical structure into segments in said medical images (Segmentation, column 6, lines 52-57); and

c. using the obtained medical images, planning the result of the orthopedic surgical procedure to be performed on the anatomical structure, so output images are produced, wherein the obtained output images comprise at least one feature selected from the group consisting of: a plurality of calibrated organs; a plurality of organ segments; a plurality of calibrated artificial elements; and at least one superposition of said calibrated artificial elements on said calibrated organs or organ segments (Figure 4).

7-2. Regarding claim 2, Krause et al. further disclose comprising dynamic rendering of medical device from pre defined members, the method allowing dynamic rendering of medical devices with a pre defined relationship, wherein two or more members can be integrated to one

member in runtime according to a predefined rule (multifunctional markers 110, column 10, line 25-28).

7-3. Regarding claim 3, Krause et al. further disclose wherein said medical images are X-ray images (regular X-ray images, column 6, lines 42-51).

7-4. Regarding claim 4, Krause et al. further disclose wherein said medical images are a combination of plurality of imaging techniques (fusing selective volumetric MRI/CAT scan data, column 8, lines 4-14).

7-5. Regarding claim 5, Krause et al. further disclose wherein said medical images comprise a plurality of views of said anatomical structure (a series of two-dimension representations of the patient's bone, column 6, lines 42-51).

7-6. Regarding claim 6, Krause et al. further disclose wherein the obtaining step comprises transforming of said medical images to digital images (until the projections of the 3D bone model 84, 86 match the X-ray or other images 83 of the patient's bone, column 7, lines 21-44).

7-7. Regarding claim 7, Krause et al. further disclose wherein said obtaining includes composing of several images of the same anatomical structure into a full-length view of said anatomical structure (use several regular X-ray images of the patient, column 6, lines 42-51).

7-8. Regarding claim 8, Krause et al. further disclose wherein the obtaining step comprises calibrating of images (An additional level of free-form deformation may be added for additional accuracy, column 7, lines 45-51).

7-9. Regarding claim 9, Krause et al. further disclose wherein said calibrating comprises registration of different views (to more closely match the two-dimensional segmented bone images, column 7, lines 9-17).

7-10. Regarding claim 10, Krause et al. further disclose wherein said calibrating comprises dimension and orientation calibration (the 3D template bone model 88 is reshaped to resemble the patient's actual bone 82, column 7, lines 9-17).

7-11. Regarding claim 11, Krause et al. further disclose wherein said calibrating comprises image enhancements comprising brightness and contrast adjustments, and edge detection (The software then determines how the template bone model should be altered to more accurately depict the patient's actual misaligned bone, column 7, lines 5-8).

7-12. Regarding claim 12, Krause et al. further disclose wherein the segmenting step is performed in at least one of a group of ways, comprising: manual performance by a medical expert, automatic performance, wherein the anatomical structure segments are segmented according to predefined rules, and semi-automatic performance, wherein the segmenting step is performed automatically with the assistance of a medical expert (Segmentation may be accomplished using a light board and digitizing stylus, column 6, lines 54-57).

7-13. Regarding claim 13, Krause et al. further disclose wherein the planning step comprises simulating different positioning of said anatomical structure segments (determine the appropriate locations, column 10, lines 8-17).

7-14. Regarding claim 14, Krause et al. further disclose wherein said different positioning of said anatomical structure segments relates to reducing of fractures during trauma treatment (apply the present system to obtain an exact realignment of the fractured bone, column 17, lines 34-40).

7-15. Regarding claim 15, Krause et al. further disclose wherein said different positioning of said anatomical structure segments relates to pre designed osteotomy treatments (determine the

appropriate locations for the double osteotomy or other multiple orthopedic procedures, column 10; lines 8-17).

7-16. Regarding claim 16, Krause et al. further disclose wherein said artificial elements comprising implants, in the manner that superposition of implants and said segmented anatomical structure over non-segmented fragments of said anatomical structure is provided (multifunctional markers 110, column 10, line 25-28).

7-17. Regarding claim 18, Krause et al. further disclose comprising a step of choosing a plurality of said fixation elements from a predefined database (the guides and markers 110 have already been modeled by the planning computer, column 10, lines 34-42).

7-18. Regarding claim 19, Krause et al. further disclose comprising rules for correct positioning of said fixation elements so incorrect positioning of said fixation elements is prevented (determine the appropriate locations, column 10, lines 8-17).

7-19. Regarding claim 20, Krause et al. further disclose wherein said planning comprises producing and storing the output images and planning reports of a plurality of alternatives of said steps of segmenting and planning, for the purpose that the best alternative for medical treatment is selected from said alternatives; said planning report comprising part definition of said calibrated artificial elements selected for the treatment as well as patient information (determine the appropriate locations, column 10, lines 8-17); said planning report comprising part definition of said artificial elements selected for the treatment as well as patient information (preliminary surgical plan, column 10, lines 46-62).

7-20. Regarding claim 21, Krause et al. further disclose additionally comprising a step of providing hard copies of said output images and said planning reports of a selected set of said

alternatives (The surgical plan may be sent to the surgeon using various media types, column 11, lines 19-27).

7-21. Regarding claim 22, Krause et al. further disclose additionally comprising a step of communicating said output images and said planning reports to a plurality of remote users (to remotely access other experts, column 2, lines 48-58).

7-22. Regarding claim 23, Krause et al. disclose an apparatus for pre planning and simulating of an orthopedic surgical procedure to be performed on an anatomical structure, using medical images of the anatomical structure, the apparatus comprising;

a. segmenting means for defining and marking anatomical structure segments in the medical images of the anatomical structure (Segmentation, column 6, lines 52-57);

b. planning means for planning the result of said orthopedic surgical procedure to be performed on the anatomical structure, using the medical images of the anatomical structure, the planning means comprising means for producing output images; wherein said output images comprise at least one feature selected from the group consisting of a plurality of calibrated organs; a plurality of organ segments; a plurality of calibrated artificial elements; and at least one superposition of said calibrated artificial elements on said calibrated organs and organ segments (Figure 4);

c. a memory for storing said medical images and a desired result (a planning computer ... has developed a detailed preliminary surgical plan, column 11, lines 15-19); and,

d. a display for displaying said medical images and said output images (The surgeon can preferably view the 3D computer simulation or other plan of the surgery, column 11, lines 19-27).

7-23. Regarding claim 24, Krause et al. further disclose comprising means for dynamic rendering of medical device from pre defined members, allowing dynamic rendering of medical

devices with a pre defined relationship, wherein two or more members can be integrated to one member in runtime according to a predefined rule (multifunctional markers 110, column 10, line 25-28).

7-24. Regarding claim 25, Krause et al. further disclose wherein the medical images are X-ray images (regular X-ray images, column 6, lines 42-51).

7-25. Regarding claim 26, Krause et al. further disclose wherein the medical images are combination of a plurality of imaging techniques (fusing selective volumetric MRI/CAT scan data, column 8, lines 4-14).

7-26. Regarding claim 27, Krause et al. further disclose wherein the medical images comprise a plurality of views of the same anatomical structures (a series of two-dimension representations of the patient's bone, column 6, lines 42-51).

7-27. Regarding claim 28, Krause et al. further disclose additionally comprising means for transforming said medical images to digital images (until the projections of the 3D bone model 84, 86 match the X-ray or other images 83 of the patient's bone, column 7, lines 21-44).

7-28. Regarding claim 29, Krause et al. further disclose additionally comprising means for composing of several images of the same anatomical structure into a full-length view of said anatomical structure (use several regular X-ray images of the patient, column 6, lines 42-51).

7-29. Regarding claim 30, Krause et al. further disclose additionally comprising calibration means for images (An additional level of free-form deformation may be added for additional accuracy, column 7, lines 45-51).

7-30. Regarding claim 31, Krause et al. further disclose wherein the calibration means are also utilized for registration of different views (to more closely match the two-dimensional segmented bone images, column 7, lines 9-17).

7-31. Regarding claim 32, Krause et al. further disclose wherein the calibration means are also utilized for dimension and orientation calibration (the 3D template bone model 88 is reshaped to resemble the patient's actual bone 82, column 7, lines 9-17).

7-32. Regarding claim 33, Krause et al. further disclose wherein the calibration means are also utilized for image enhancements (The software then determines how the template bone model should be altered to more accurately depict the patient's actual misaligned bone, column 7, lines 5-8).

7-33. Regarding claim 34, Krause et al. further disclose wherein the calibration means are also utilized for correction of image distortions (The software then determines how the template bone model should be altered to more accurately depict the patient's actual misaligned bone, column 7, lines 5-8).

7-34. Regarding claim 35, Krause et al. further disclose wherein the segmenting means are manually operated by a medical expert or wherein the segmenting means are automatically operated according to predefined rules, or wherein the segmenting means are operated semi-automatically in the manner that the segmenting step is performed automatically with the assistance of a medical expert (Segmentation may be accomplished using a light board and digitizing stylus, column 6, lines 54-57).

7-35. Regarding claim 36, Krause et al. further disclose wherein the planning means are additionally utilized for simulating different positioning of said anatomical structure segments (determine the appropriate locations, column 10, lines 8-17).

7-36. Regarding claim 37, Krause et al. further disclose wherein the planning means are utilized for simulating reduction of fractures during trauma treatment (apply the present system to obtain an exact realignment of the fractured bone, column 17, lines 34-40).

7-37. Regarding claim 38, Krause et al. further disclose wherein said different positioning of said anatomical structure segments relates to pre designed osteotomy treatments for deformed anatomical structures (determine the appropriate locations for the double osteotomy or other multiple orthopedic procedures, column 10, lines 8-17).

7-38. Regarding claim 39, Krause et al. further disclose wherein the artificial elements comprise implants, in the manner that superposition of implants and said segmented anatomical structure over non-segmented fragments of said anatomical structure is provided (multifunctional markers 110, column 10, line 25-28).

7-39. Regarding claim 41, Krause et al. further disclose comprising a predefined database comprising predefined sets of fixation elements (the guides and markers 110 have already been modeled by the planning computer, column 10, lines 34-42).

7-40. Regarding claim 42, Krause et al. further disclose comprising means for correct positioning of said fixation elements so incorrect positioning of said fixation elements is prevented (determine the appropriate locations, column 10, lines 8-17).

7-41. Regarding claim 43, Krause et al. further disclose additionally comprising a means for producing and storing planning reports of plurality of alternatives, for the purpose that the best alternative for medical treatment is selected from said alternatives (determine the appropriate locations, column 10, lines 8-17), said planning reports comprising part definition of said calibrated artificial elements selected for the medical treatment and patient information (preliminary surgical plan, column 10, lines 46-62).

7-42. Regarding claim 44, Krause et al. further disclose additionally comprising means for creating hard copies of said output images and said planning reports of a selected set of said

alternatives (The surgical plan may be sent to the surgeon using various media types, column 11, lines 19-27).

7-43. Regarding claim 45, Krause et al. further disclose additionally comprising communicating means for communicating said output images and said planning reports to remote users (to remotely access other experts, column 2, lines 48-58).

Applicants' Arguments

8. Applicants argue the following:

8-1. Claim Rejection - 35 USC 112

(1) "Claims 24 and 29 are currently amended so as to recite: "The apparatus according to claim 23...", thus making each of claims 24 and 29 an apparatus claim dependent on independent apparatus claim 23" (Page 9, Response).

(2) "Applicant now amended claims 9-11, 14-15, 18-19, 20-22, and 23-45" (Page 9, paragraph 5, Response).

8-2. Claim Rejection - 35 USC 102

(3) "However, Krause falls short of disclosing or even hinting at the idea of a method where medical images of an anatomical structure an orthopedic surgical procedure is to be performed on are obtained, displayed, segmented, and used for planning the result of the orthopedic surgical procedure to be performed on the anatomical structure, as taught by the present invention, and defined by claim 1. It is thus believed that claim 1 is both novel and inventive over the prior art and respectfully maintained that the claim should be allowed" (Page 12, paragraph 4, Response).

(4) "It is thus believed that claim 23 is both novel and inventive over the prior art and respectfully maintained that the claim should be allowed" (Page 13, paragraph 2, Response).

Response to Arguments

9. Applicants' arguments have been fully considered.

9-1. Applicants' argument (1) is persuasive. The rejections of claims 24 and 29 under 35 U.S.C. 112, first paragraph, in Office Action dated September 8, 2006, have been withdrawn.

9-2. Applicants' argument (2) is persuasive. The rejections of claims 9-11, 14-15, 18-19, 20-22, and 23-45 under 35 U.S.C. 112, second paragraph, in Office Action dated September 8, 2006, have been withdrawn.

9-3. Applicants' arguments (3)-(4) are not persuasive. Krause et al. disclose at column 6, lines 41-50, "Rather than generating the 3D model of the improperly aligned bone directly from MRI or CAT data as performed by conventional systems, the surgeon or other technician may alternatively use several regular X-ray images of the patient 66 (which are typically taken before any surgery). Preferably, at least a lateral and an AP (anterior-posterior) X-ray are taken of the patient's bone. The result of this imaging procedure is a series of two-dimensional representations of the patient's bone from various angles." In other words, Krause et al. expressly disclose medical images of an anatomical structure an orthopedic surgical procedure is to be performed on are obtained, displayed, segmented, and used for planning the result of the orthopedic surgical procedure to be performed on the anatomical structure.

Conclusion

10. Applicants' amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicants are reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

11. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Herng-der Day whose telephone number is (571) 272-3777. The Examiner can normally be reached on 9:00 - 17:30.

Any inquiry of a general nature or relating to the status of this application should be directed to the TC 2100 Group receptionist: (571) 272-2100.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Kamini S. Shah can be reached on (571) 272-2279. The fax phone numbers for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Herng-der Day
April 16, 2007 H.D.

KAMINI SHAH
SUPERVISORY PATENT EXAMINER